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10/585,430	01/07/2009	Eric Mangiardi	37621/51001	4712

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EXAMINER	
STRANSKY, KATRINA M	
ART UNIT	PAPER NUMBER
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,430	MANGIARDI ET AL.	
	Examiner	Art Unit	
	KATRINA STRANSKY	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *2,3,11 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-10, 12-22, 24-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This action in entered in response to Applicant's Amendment and Reply of April 5, 2011.

Claims 1, 4, 5, 10, 12, 13, 16, 17, 20, 25 and 29-30 have been amended. Claims 2-3, 11 and 23 were previously canceled.

Currently, Claims 1, 4-10, 12-22 and 24-31 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-5, 13-17, 25-28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bachmann et al, US Patent No. 5,954,729 ("Bachmann").

3. Regarding claims 1 and 13, Bachmann discloses a stent deployment device (1, Fig. 1) comprising a support member configured to abut the user's hand (35, 37, Fig. 1); a longitudinally extending outer tubular member (9, Fig. 1) having proximal and distal ends (Fig. 1), the distal end configured to receive the stent such that the stent is slidably disposed in the outer tubular member (stent 33, Fig. 5); an inner tubular member (7, Figs. 3 and 4) having distal and proximal ends (Figs. 3 and 4); the distal end of the inner tubular member comprising a tip (19, Figs. 3 and 4); the inner tubular member is

coupled with the support member (Figs. 1 and 3) and at least a portion of the inner tubular member is disposed within the outer tubular member such that the inner tubular member is longitudinally and axially displaceable relative to the outer tubular member (Fig. 6). Bachmann also discloses a deployment mechanism coupled with the outer tubular mechanism to allow staged release of the stent (operating system 3, Fig. 6), the deployment mechanism comprising first release member (43, Fig. 6) to at least partially move the outer tubular member proximally and longitudinally relative to the inner tubular member (col. 7, lines 9-30), and a second release member (41, Fig. 6) positioned proximal to the first release member and operably connected to the first release member to move the outer tubular member relative to the inner tubular member (Fig. 6, col. 7, lines 9-30); wherein the first and second release members are configured to be serially retracted to provide staged release of the stent such that retracting the second release member moves the first release member and the outer tubular member proximally and longitudinally relative to the inner tubular member from a first position to a second position to partially deploy the stent, and subsequent retraction of the first release member moves the outer tubular member proximally and longitudinally relative to the inner tubular member from a second position to a third position to fully deploy the stent (col. 7, lines 9-30).

4. Bachmann also discloses a stent (33) having proximal and distal ends (Figs. 1 and 5) where the tip of the inner tubular member engages the proximal end of the stent for advancing the stent toward the distal end of the outer tubular member as the first

and second release members move toward the support member (Figs. 5 and 6, col. 7, lines 9-30).

5. Regarding claims 4 and 16, Bachmann discloses a safety member (49, Fig. 5) for preventing movement of the first release member and the outer tubular member toward the support member beyond a predetermined position of the outer tubular member relative to the inner tubular member (col. 7, lines 9-30).

6. Regarding claims 5 and 17, Bachmann discloses that movement of the first release member from the first position to the predetermined position exposes at least a portion of the stent outwardly of the distal end of the outer tubular member (Fig. 5, col. 7, lines 9-30).

7. Regarding claim 14, Bachmann discloses that a portion of the stent is exposed outwardly of the distal end of the outer tubular member (Fig. 5, col. 7, lines 9-30).

8. Regarding claim 15, Bachmann discloses that the stent is deployed from the distal end of the outer tubular member (Fig. 5, col. 7, lines 9-30).

9. Regarding claim 25, Bachmann discloses a method for delivering a stent (col. 7, lines 9-30) comprising providing a delivery device (1, Fig. 6, col. 7, lines 9-30) including a support member (35, 37, Fig. 1); an outer tubular member (9, Fig. 1) having proximal and distal ends (Fig. 1), the distal end configured to receive the stent (33, Fig. 5) such that the stent is slidably disposed within the outer tubular member (Fig. 5); an inner tubular member (7, Fig. 3 and 4) having distal and proximal ends (Figs. 3 and 4); the distal end of the inner tubular member comprising a tip (19, Fig. 3 and 4); the inner tubular member is coupled with the support member (Fig. 1) and at least a portion of the

inner tubular member is disposed within the outer tubular member such that the inner tubular member is longitudinally and axially displaceable relative to the outer tubular member (Fig. 6), and a deployment mechanism coupled with the outer tubular mechanism (operating system 3, Fig. 6) to allow staged release of the stent, the deployment mechanism comprising first release member (43, Fig. 6) to at least partially move the outer tubular member relative to the inner tubular member, and a second release member (41, Fig. 6) proximal to the first release member and operably connected to the first release member to move the outer tubular member relative to the inner tubular member (col. 7, lines 9-30), wherein the first and second release members are configured to be serially retracted to provide staged release of the stent; slidably disposing a stent (33) having a proximal end and a distal end (Fig. 1) within a distal portion of the outer tubular member and around a distal portion of the inner tubular member (Fig. 5), wherein the tip of the inner tubular member engages the proximal end of the stent to advance the stent toward the distal end of the outer tubular member as the outer tubular member moves toward the support member relative to the inner tube (Figs. 3, 4, and 5, col. 7, lines 9-30); and positioning the distal portion of the outer tubular member within the anatomical lumen of the patient at a desired location (col. 7, lines 9-25); retracting the second release member in a direction toward the support member to thereby retract the first release member and the outer tubular member relative to the inner tubular member from a first position to a second position to partially deploy the distal end of the stent (col. 7, lines 9-30, Figs. 5 and 6); and retracting the first release member in a direction toward the support member and toward the second

release member to thereby retract the outer tubular member relative to the inner tubular member from a second position to a third position to completely deploy the stent in the anatomical lumen of the patient (col. 7, lines 9-30, Figs. 5 and 6).

10. Regarding claim 26, Bachmann discloses that a portion of the stent is exposed outwardly of the distal end of the outer tubular member (Fig. 5, col. 7, lines 9-30).

11. Regarding claim 27, Bachmann discloses that the stent is deployed from the distal end of the outer tubular member (Fig. 5, col. 7, liens 9-30).

12. Regarding claim 28, Bachmann discloses preventing movement of the first release member and the outer tubular member toward the support member beyond a predetermined position of the outer tubular member relative to the inner tubular member (47 and 49 prevent movement of the release members beyond a predetermined position, Fig. 6, col. 7, lines 9-30).

13. Regarding claim 31, Bachmann discloses that the deployment mechanism can be operable without initially disengaging a safety mechanism (col. 7, lines 9-30).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachmann.

16. Regarding claims 6 and 18, Bachmann discloses the claimed invention except for the amount of the stent exposed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to expose about 5 to about 95 percent of the stent since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

17. Claims 8, 20, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachmann in view of Bui et al, US Patent No. 6,413,269 B1.

18. Regarding claims 8, 20 and 29, Bachmann discloses that an endoscope or telescope can be used to check the locating of the delivery device, but does not explicitly disclose details of the endoscope. However, Bui et al teaches an elongated viewing device having a proximal and distal end ("endoscope" col. 4, lines 10-25), slidably disposed in the outer tubular member (col. 4, lines 10-25). While Bui et al does not specifically disclose the endoscope extending proximally of the proximal end of the outer tubular member, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the endoscope in a manner such that the proximal end of the viewing device extends outwardly of the proximal end of the outer tubular member in order to allow a user to engage the device with his or her eye, whereas if the proximal end of the endoscope did not extend proximal to the proximal end of the outer tubular member, the endoscope would require additional components for actual use.

19. Claims 7, 9, 10, 12, 19, 21, 22, 24, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachmann in view of Derus et al, US Publication No. 2002/0183827 (hereinafter referred to as Derus).

20. Regarding claims 7 and 19, Bachmann lacks the teaching that the safety member comprises a removable tab disposed between the support member and the outer tubular member. However, Derus teaches a safety member comprising a removable tab (56, Figure 6 shows the tab disposed between the distal end of the outer tubular member and the stabilizing member). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the safety member of Bachmann with the removable tab as taught by Derus in order to maintain the outer tube in position until deployment of the stent (Derus, paragraph 0043).

21. Regarding claims 9, 21 and 30, Bachmann discloses the claimed invention except for means for releasably securing the viewing device. However, Derus teaches means for releasably securing the viewing device (106). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the support of Bachmann with the securing means as taught by Derus in order to releasably secure an endoscope in order to view the stent and determine proper placement of the stent (Derus, paragraph 0053).

22. Regarding claims 10 and 22, Bachmann discloses the claimed invention except for the viewing device securing means is associated with the stabilizing member. However, Derus teaches that the securing means is associated with the stabilizing

member (see Figure 5b). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the support of Bachmann with the securing means as taught by Derus in order to releasably secure an endoscope in order to view the stent and determine proper placement of the stent (Derus, paragraph 0053).

23. Regarding claims 12 and 24, Bachmann and Derus disclose the claimed invention except for threadingly attached the clamp 106. It would have been an obvious matter of design choice to use a threaded clamp, since applicant has not disclosed that threading solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any sort of clamp, such as a press-fit clamp or a snap-fit clamp.

Response to Arguments

24. Applicant's arguments with respect to claims 1, 4-10, 12-22 and 24-31 have been considered but are moot in view of the new grounds of rejection.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATRINA STRANSKY whose telephone number is (571)270-3843. The examiner can normally be reached on Monday thru Friday, 8:00 am to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KS/
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner, Art Unit 3734